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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,814	08/27/2001	Gust H. Bardy	032580.0022.UTL	7963

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/02/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,814

Applicant(s)

BARDY ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-240 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9-11,26-62,64,69-71,86-122,124,129-131,146-182,184,189-191 and 206-240 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,5-8,12-25,63,65-68,72-85,123,125-128,132-145,183,185-188 and 192-205.

DETAILED ACTION
Election/Restrictions

1. Applicant's election without traverse of the invention defined by claims 1, 2, 4, 9-11, 26-62, 64, 69-71, 86-122, 124, 129-131, 146-182, 184, 189-191 and 206-240 in Paper No. 9 is acknowledged.

Specification

2. The disclosure is objected to because of numerous errors regarding the referencing of elements in the drawings. Furthermore, the status of the cross-referenced applications on page 1 of the specification must be updated. Correction is required. See MPEP § 608.01(b).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 2, 4, 9-11, 26-62, 64, 69-71, 86-122, 124, 129-131, 146-182, 184, 189-191 and 206-240 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14, 33-36 and 48-59 of copending Application No. 09/940,468. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are merely broader than the claims in the '468 application. Once an applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 9-11, 26-36, 42, 43-53, 59, 60, 121, 122, 124, 129-131, 146-156, 162-173, 179 and 180 are rejected under 35 U.S.C. 102(b) as being anticipated by Mower et al. (Pat. No. 4,765,341).

Regarding claim 1 and claims with related limitations, while the functional language concerning the use of a subcutaneously implanted assembly outside a patient's ribcage between the third and twelfth ribs was considered, statements of intended use and statements pertaining to location of apparatus within the body will have no effect in saliently distinguishing over the apparatus of the prior art. Mower et al. disclose a lead electrode assembly 10 comprising an electrode 12.

Concerning claim 4, the effective energy for shocking a patient's heart depends upon a number of factors including patient age and concomitant heart size, electrode location, defibrillation pulse parameters, etc.. The applicants are not claiming a means to produce a shock of 50 to 75 J, simply an electrode assembly. The examiner considers the electrode of Mower et al. to be suitable for emitting an effective shocking energy of 50 to 75 J.

Regarding claims 9 and 10, the examiner considers the electrode of Mower et al. to be capable of receiving physiological information from the patient through sensors. It is well-known in the art that an electrode that can stimulate or shock, can also be used to sense physiological signals. Furthermore, the applicants are not positively reciting the sensors.

Regarding claim 11 and claims with similar limitations, the examiner considers a single strand of wire in the woven mesh material to constitute a non-planar portion of the electrode.

Regarding claims 26-30, statements concerning electrode position with respect to the body will have no effect in distinguishing over the apparatus of the prior art.

Regarding claim 31, the examiner considers either of silastic layers 18 and 26 to represent a backing layer.

Concerning claim 36, the examiner considers either of layers 18 and 26 to represent a skirt with the electrode sandwiched there between as can be seen in Fig. 4.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 37-41, 54-58, 157-161 and 174-178 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower et al. (Pat. No. 4,765,341).

In regards to claim 37, although Mower et al. do discuss a cover coupled to the electrode (either of layers 18 or 26), they do not explicitly discuss a *molded* cover coupled to the electrode. The applicants, however, do not give any criticality to the use of a molded cover over that of any other manufacture. Clearly the silastic material discussed by Mower et al. is suitable for molding and the use of molded articles for medical electrodes is old and well-known in the art. Given the lack of criticality by the applicants and the suitability of the Mower et al. material to the molding process, those of ordinary skill in the art would have considered a molded cover to be a matter of obvious design.

Concerning claim 54 and claims with similar limitations, the examiner considers a typical lead for use in the Mower et al. system to fall in the range recited and takes Official Notice to this effect. Likewise concerning claims 55 and 56, no criticality has

been recited by the applicant for the particular length of lead used. The examiner considers it a matter of obvious design as to what the final lead length should be, dependent upon the situation at hand (e.g., whether or not the patient was an adult or an infant).

Concerning claims 57 and 58 and claims with similar limitations, the applicant appears to be defining the invention in terms of non-elements of the invention. The applicant is not claiming a set of leads with a plurality of preset lengths varying by approximately 10 cm –simply that the lead used is one of a plurality of preset lengths. Whether a lead falls into this category is simply a matter of how many different leads a manufacturer may produce.

9. Claims 61, 62, 64, 69-71, 86-120, 181, 182, 184, 189-191 and 206-240 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower et al. in view of Mader et al. (Pat. No. 5,312,441).

Regarding claim 61, Mower et al. do not discuss the use of an electrode on the housing. Mader et al., however, disclose that a number of different electrode options exist for the designer to choose from, including housing electrodes in combination with epicardial electrodes (note col. 4, lines 41-48). The use of the housing as an electrode is old and well-known in the defibrillation art by those of ordinary skill.

Regarding claim 96, note the comments above made in the rejection of claim 37.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

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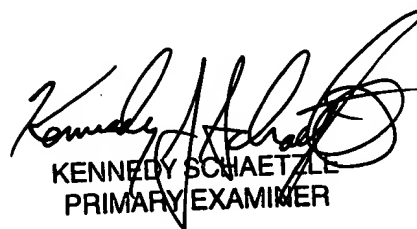
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS

January 25, 2004



KENNEDY SCHAEETZLE
PRIMARY EXAMINER